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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/312,485	05/17/1999	PATRICE DEBREGEAS	065691/0163	2681

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 06/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/312,485

Applicant(s)

DEBREGEAS ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/4/2001, 8/28/01, 3/20/2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Pursuant to the Grant of the Petition filed under 37 CFR §1.81, Paper No. 16, the finality of the last Office Action is withdrawn.
2. Claims 1-21 are pending.
3. Applicant's Amendment filed on August 28, 2001, Paper No. 11 has been entered. Applicant's arguments filed on August 28, 2001 were fully addressed in the Advisory Action filed on September 21, 2001, Paper No. 12.
4. Any rejection that is not addressed in this Office Action is considered withdrawn.

### ***Pending Rejections***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-2, 4-5, 9-13, 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Cingotti US Patent 5,427,800 (IDS, filed on 2/3/99, Paper No.6).

Cingotti discloses a process of coating micro granules having dimensions between 0.1-1 millimeter (100-1000microns) with a plant extract or tincture (*example 1-2*). Cingotti specifically discloses silica crystalline powder having 210-500 microns coated with alcoholic tincture of passiflora (*col 3 lines 40-65*). Cingotti's sorbital microgranules are analogous to the instant neutral core and possess the same particle size (*col 4, lines 5-9*). Cingotti also discloses the use of other granules such as microcrystalline cellulose (*example 4, claim 1*) being coated with extract of an active ingredient (such as harpogophytum root or passiflora) (*examples 2-3*); as well as , the use of binders such as sorbitol powder to provided compressibility and sufficient bulk

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density of his granule formulations (*col 4 lines 1-30*). The coated granules of Cingotti are then dried and gauged to a predetermined size (*claims 1, 6*). Cingotti uses sorbitol or ethanol as his solvent of choice (*example 2-3*). Therefore, Cingotti meets the limitations of the instant claims.

6. Claims 3, 6-8, 14-15, 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Cingotti US Patent 5,427,800 (IDS filed on 2/3/99, Paper No. 6) and Menzi et al US Patent 6,056,949 in view of Breitenbach et al US Patent 6,120,802 (PTO-892 filed on 10/11/00).

Cingotti discloses a process of coating micro granules with a plant extract or tincture having the same particle size as the instant neutral core (*col 4, lines 1-30, example 1-2*). Cingotti also discloses the use of other granules such as microcrystalline cellulose (*example 4, claim 1*) being coated with extract of an active ingredient (such as harpogophytum root or plassiflora) (*examples 2-3*). Cingotti fails to teach the use of a delaying or flavoring agent.

Menzi et al teaches spherical granules as core material (such as maltodextrin, lactose or sucrose) that are coated with an emulsion which is sprayed on the granules (*col 2, lines 6-30, example 1*). The emulsion of Menzi can comprise a sugar, plant extract, protein or combination thereof (*col 2, lines 20-25; col 2, lines 40-47*). Menzi specifically teach the use of flavorant or odorants in his coating emulsion that can contain various modified cellulose (encompassing hydroxymethylcellulose), plant extract, and/or synthetic material such as polyvinyl pyrrolidone(PVP) (*col 6, lines 50-56; col 2, lines 46-48*). Menzi also teaches water and ethanol as their solvent of choice(*col*

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2, *line 28-30*). Menzi et al fail to teach the use of a delaying agent containing copolymers of methacrylic acid or the use of a plasticizer or binders in their formulations.

Breitenbach et al teach methods of formulating controlled release formulations of various types of pharmaceutically active agents such as herbal substances including Ginkgo biloba having multilayers of coating, (*col 5 line 65*). Breitenbach et al specifically teach the use of various conventional additives including plasticizer and binders such as hydroxypropylcellulose, PVP, acrylic acid copolymers to formulate their multi layer compositions, (*col 9 lines 1-37*). Breitenbach et al also teaches conventional methods of coating by treating their formulation in a coating pan or fluidized bed apparatus, (*col 7 lines 29-30*). Breitenbach fails to specifically describe a core material consisting of a sugar, cellulose, lactose or a mixture thereof.

Cingotti, Menzi and Breitenbach teach methods of preparing oral dosage formulations, thus, their teachings are viewed to be in the same field of endeavor.

Although Cingotti does not teach the use of a flavorant or a delaying agent in their coating extract mixture, it would have been obvious to one of ordinary skill in the art of drug dosage forms at the time of invention to incorporate a flavorant comprising plant extract, as taught by Menzi, and further add a plasticizer, a binder and a delaying agent of choice including methacrylic acid copolymers, as taught by Breitenbach, into Cingotti's coating mixture, and then apply the resultant coating mixture on the granules by conventional methods known in the art, to formulate a controlled release formulation of Cingotti's granules. One of ordinary skill in the art would have been motivated to do

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such modifications to improve the pharmacokinetics properties of Cingotti's preparations, and subsequently improves the patient's compliance.

Finally, absence of showing a criticality, optimizing concentrations of diluents and the components of core material within a dosage form does not impart patentability because they are achievable by routine experimentation and optimization.

***Conclusion***

7. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, JD can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200

ss  
May 29, 2002